

### **Amendments of the Claims:**

A detailed listing of all claims in the application is presented below. This listing of claims will replace all prior versions, and listings, of claims in the application. All claims being currently amended are submitted with markings to indicate the changes that have been made relative to immediate prior version of the claims. The changes in any amended claim are being shown by ~~strike through~~ (for deleted matter) or underlined (for added matter).

1. (Cancelled)
2. (Cancelled)
3. (Cancelled)
4. (Cancelled)
5. (Cancelled)
6. (Cancelled)
7. (Cancelled)
8. (Cancelled)
9. (Cancelled)
10. (Currently Amended) An ultra miniature integrated cardiac pacemaker requiring no chest incision, that can be implanted in a heart by attaching the pacemaker to a tip of a catheter and extracting the catheter after implanting, comprising:
  - a) a control unit that outputs at least one control signal;
  - b) a heart stimulating means that responds to the control signal and electrically stimulates heart tissue;

c) an electrocardiographic information detecting means that detects a plurality of electrocardiographic information and outputs the electrocardiographic information to the control unit; and

d) a power unit that supplies power to the pacemaker;

wherein the control unit outputs the control signal based on the electrocardiographic information;

wherein the control unit includes a stimulation timing determining means that decides the timing of stimulation to generate control signals, and a stimulation timing changing means that changes the timing of stimulation to generate control signals;

wherein the control unit changes the stimulation timing when certain conditions are fulfilled;

wherein the power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels;

wherein the biological fuel cell comprises an anode ~~electrode~~ and a cathode;

wherein the anode comprises an anode electrode and ~~coated with~~ an immobile layer ~~formed on a surface of the anode electrode~~ by immobilization of mediators and oxidative enzymes for biological fuels, wherein said immobile layer prevents oxygen existing in a biological body from contacting said anode electrode; ~~and a~~

wherein the cathode ~~electrode coated with a~~ comprises a cathode electrode and a coating material formed on a surface of the cathode electrode, wherein said coating material is capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions;

wherein the biological fuel cell uses an electrolyte solution selected from the group consisting of blood; body fluid; and blood and body fluid, and utilizes biological fuels and oxygen in the electrolyte solution; and

wherein said anode ~~electrode~~ and said cathode ~~electrode~~ are adapted to contact the electrolyte solution.

11. (Currently Amended) An ultra miniature integrated cardiac pacemaker requiring no chest incision, that can be implanted in a heart by attaching the pacemaker to a tip of a catheter and extracting the catheter after implanting, comprising:

- a) a control unit that outputs at least one control signal;
- b) a heart stimulating means that responds to the control signal and electrically stimulates heart tissue;
- c) an electrocardiographic information detecting means that detects a plurality of electrocardiographic information and outputs the electrocardiographic information to the control unit;
- d) a transmitting means that modulates the electrocardiographic information and the control signal and sends the modulated electrocardiographic information and the modulated control signal outside; and
- e) a power unit that supplies power to the pacemaker;

wherein the control unit outputs the control signal based on the electrocardiographic information;

wherein the control unit includes a stimulation timing determining means that decides the timing of stimulation to generate control signals, and a stimulation timing changing means that changes the timing of stimulation to generate control signals;

wherein the control unit changes the stimulation timing when certain conditions are fulfilled;

wherein the power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels;

wherein the biological fuel cell comprises an anode ~~electrode and a cathode;~~

~~wherein the anode comprises an anode electrode and~~ coated with an immobile layer formed on a surface of the anode electrode by immobilization of mediators and oxidative enzymes for biological fuels, wherein said immobile layer prevents oxygen existing in a biological body from contacting said anode electrode; ~~and a~~

~~wherein the cathode electrode coated with a~~ comprises a cathode electrode and a coating material formed on a surface of the cathode electrode, wherein said coating material is capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions;

wherein the biological fuel cell uses an electrolyte solution selected from the group consisting of blood; body fluid; and blood and body fluid, and utilizes biological fuels and oxygen in the electrolyte solution; and

wherein said anode ~~electrode and~~ said cathode ~~electrode are~~ adapted to contact the electrolyte solution.

12. (Currently Amended) An ultra miniature integrated cardiac pacemaker requiring no chest incision, that can be implanted into a heart by attaching the pacemaker to a tip of a catheter and extracting the catheter after implantation, comprising:

a) a control unit that outputs at least one control signal;

b) a heart stimulating means that responds to the control signal and electrically stimulates heart tissue;

c) an electrocardiographic information detecting means that detects a plurality of electrocardiographic information and outputs the electrocardiographic information to the control unit;

d) a receiving means that demodulates information transmitted from an exterior;  
and

e) a power unit that supplies power to the pacemaker;

wherein the pacemaker is designed such that information sent from outside is input into the control unit;

wherein the control unit outputs the control signal based on information selected from the group consisting of information sent from outside; electrocardiographic information; and a combination of information sent from outside and electrocardiographic information;

wherein the control unit includes a stimulation timing determining means that decides the timing of stimulation to generate control signals, and a stimulation timing changing means that changes the timing of stimulation to generate control signals;

wherein the control unit changes the stimulation timing when certain conditions are fulfilled;

wherein the power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels;

wherein the biological fuel cell comprises an anode ~~electrode~~ and a cathode;

wherein the anode comprises an anode electrode and coated with an immobile layer formed on a surface of the anode electrode by immobilization of mediators and oxidative enzymes for biological fuels, wherein said immobile layer prevents oxygen existing in a biological body from contacting said anode electrode; ~~and a~~

wherein the cathode electrode-coated with a  
comprises a cathode electrode and a  
coating material formed on a surface of the cathode electrode, wherein  
said coating material is capable of preventing permeation of reactive  
substances other than oxygen and allowing permeation of oxygen and  
hydrogen ions;

wherein the biological fuel cell uses an electrolyte solution selected from the  
group consisting of blood; body fluid; and blood and body fluid, and  
utilizes biological fuels and oxygen in the electrolyte solution; and

wherein said anode ~~electrode~~ and said cathode ~~electrode~~ are adapted to contact the  
electrolyte solution.

13. (Currently Amended) An ultra miniature integrated cardiac pacemaker requiring no chest  
incision, that can be implanted into a heart by attaching the pacemaker to a tip of a  
catheter and extracting the catheter after implantation, comprising:

- a) a control unit that outputs at least one control signal;
- b) a heart stimulating means that responds to the control signal and electrically  
stimulates heart tissue;
- c) an electrocardiographic information detecting means that detects a plurality of  
electrocardiographic information and outputs the electrocardiographic  
information to the control unit;
- d) a transmitting means that modulates the electrocardiographic information and  
control signal and sends the modulated electrocardiographic information  
and the modulated control signal outside;
- e) a receiving means that demodulates information transmitted from outside; and
- f) a power unit that supplies the driving power;

wherein the pacemaker is designed such that information sent from outside is input into the control unit;

wherein the control unit outputs the control signal based on information selected from the group consisting of information sent from outside; electrocardiographic information; and a combination of information sent from outside and electrocardiographic information;

wherein the control unit includes a stimulation timing determining means that decides the timing of stimulation to generate control signals, and a stimulation timing changing means that changes the timing of stimulation to generate control signals;

wherein the control unit changes the stimulation timing when certain conditions are fulfilled;

wherein the power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels;

wherein the biological fuel cell comprises an anode ~~electrode and a cathode;~~

wherein the anode comprises an anode electrode and coated with an immobile layer formed on a surface of the anode electrode by immobilization of mediators and oxidative enzymes for biological fuels, wherein said immobile layer prevents oxygen existing in a biological body from contacting said anode electrode; ~~and a~~

wherein the cathode ~~electrode coated with a~~ comprises a cathode electrode and a coating material formed on a surface of the cathode electrode, wherein said coating material is capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions;

wherein the biological fuel cell uses an electrolyte solution selected from the group consisting of blood; body fluid; and blood and body fluid, and utilizes biological fuels and oxygen in the electrolyte solution; and

wherein said anode ~~electrode~~ and said cathode ~~electrode~~ are adapted to contact the electrolyte solution.

14. (Withdrawn) A cardiac pacing system comprising an ultra miniature integrated cardiac pacemaker placed in the atrial myocardium, wherein the ultra miniature integrated cardiac pacemaker comprises:

a) a control unit that outputs at least one control signal, wherein the control unit comprises:

i) a stimulation timing determining means that decides a timing of stimulation to generate the control signal; and

ii) a stimulation timing changing means that changes the timing of stimulation to generate the control signal;

wherein the control unit changes the timing of stimulation to generate the control signal, if intracardiac P wave information is detected within a preset time interval;

b) a heart stimulating means that responds to the control signal and electrically stimulates the atrial myocardium;

c) an electrocardiographic information detecting means that detects a plurality of electrocardiographic information including at least intracardiac P wave information; and

d) a power unit that supplies power to the pacemaker;

wherein the power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels;



wherein the biological fuel cell comprises an anode electrode and a cathode electrode;

wherein the anode electrode is coated with immobilized oxidative enzymes for biological fuels and mediators; and

wherein the biological fuel cell uses blood and/or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in blood and/or body fluid.

15. (Withdrawn) A distributed cardiac pacing system comprising an electrocardiographic information detecting device placed in an atrial myocardium and an ultra miniature integrated cardiac pacemaker placed in a ventricular myocardium;

wherein the electrocardiographic information detecting device comprises:

- a) an electrocardiographic information detecting means that detects a plurality of electrocardiographic information including at least intracardiac P wave information;
- b) a transmitting means that modulates detected electrocardiographic information and sends information to the ultra miniature integrated cardiac pacemaker;
- c) a power unit that supplies driving power, wherein the power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels;

wherein the biological fuel cell comprises an anode electrode and a cathode electrode;

wherein the anode electrode is coated with immobilized oxidative enzymes for biological fuels and mediators;

wherein the biological fuel cell uses blood and/or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in blood and/or body fluid;

wherein the ultra miniature integrated cardiac pacemaker comprises:

- a) a receiving means that receives and demodulates the electrocardiographic information sent from the electrocardiographic information detection device;
- b) a control unit that outputs at least one control signal, wherein the said control unit comprises:
  - i) a stimulation timing determining means that decides a timing of stimulation to generate the control signal; and
  - ii) a stimulation timing changing means that changes the timing of stimulation to generate the control signal;

wherein the control unit generates the control signal when intracardiac QRS complex information is not detected within a given time after detection of intracardiac P wave information, and suppresses the control signal when QRS complex information is detected within a given time after detection of intracardiac P wave information;

- c) a heart stimulating means that responds to the control signal and electrically stimulates the ventricular myocardium; and
- d) a power unit that supplies a driving current;

wherein the power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels;

wherein the biological fuel cell comprises an anode electrode and a cathode electrode;

wherein the anode electrode is coated with immobilized oxidative enzymes for biological fuels and mediators;

wherein the biological fuel cell uses blood and/or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in blood and/or body fluid.

16. (Withdrawn) A distributed cardiac pacing system comprising a first ultra miniature integrated cardiac pacemaker placed in an atrial myocardium and a second ultra miniature integrated cardiac pacemaker placed in a ventricular myocardium,

wherein the first ultra miniature integrated cardiac pacemaker comprises:

- a) a first control unit that outputs at least one first control signal;
- b) a first heart stimulating means that responds to the first control signal and electrically stimulates the atrial myocardium;
- c) a first electrocardiographic information detecting means that detects a plurality of electrocardiographic information including at least intracardiac P wave information;
- d) a first transmitting means that modulates the electrocardiographic information and sends the information to the second ultra miniature integrated cardiac pacemaker;
- e) a first receiving means that receives and demodulates the electrocardiographic information sent from the second ultra miniature integrated cardiac pacemaker; and
- f) a first power unit that supplies driving power to the first pacemaker;

wherein the first power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels;

wherein the biological fuel cell comprises an anode electrode and a cathode electrode;

wherein the anode electrode is coated with immobilized oxidative enzymes for biological fuels and mediators;

wherein the biological fuel cell uses blood and/or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in blood and/or body fluid;

wherein electrocardiographic information sent from the second ultra miniature integrated cardiac pacemaker is input into the first control unit; and the first control unit has a stimulation timing determining means that decides a timing of stimulation to generate the first control signal, and a stimulation timing changing means that changes the timing of stimulation to generate the first control signal;

wherein the second ultra miniature integrated cardiac pacemaker comprises:

- a) a second control unit that outputs at least one second control signal;
- b) a second heart stimulating means that responds to the second control signal and electrically stimulates the ventricular myocardium;
- c) a second electrocardiographic information detecting means that detects a plurality of electrocardiographic information including at least intracardiac QRS complex information;
- d) a second transmitting means that modulates the electrocardiographic information and sends the information to the first ultra miniature integrated cardiac pacemaker;

e) a second receiving means that receives and demodulates electrocardiographic information sent by the first ultra miniature integrated cardiac pacemaker; and

f) a second power unit that supplies driving current to the second pacemaker;

wherein the second power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels,

wherein the biological fuel cell comprises an anode electrode and a cathode electrode;

wherein the anode electrode is coated with immobilized oxidative enzymes for biological fuels and mediators;

wherein the biological fuel cell uses blood and/or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in blood and/or body fluid;

wherein electrocardiographic information sent from the first ultra miniature integrated cardiac pacemaker is input into the second control unit; and the second control unit is equipped with a stimulation timing determining means that decides a timing of stimulation to generate the second control signal, and a stimulation timing changing means that changes the timing of stimulation to generate the second control signal;

wherein the first control unit generates the first control signal when intracardiac P wave information is not detected within a given time, and suppresses generation of the first control signal when intracardiac P wave information is detected within a given time;

wherein the second control unit generates the second control signal when intracardiac QRS complex information is not detected within a given time

after detection of intracardiac P wave information, and suppresses generation of the second control signal when intracardiac QRS complex information is detected within a given time after detection of intracardiac P wave information; and

wherein if the second ultra miniature integrated cardiac pacemaker detects intracardiac QRS complex information due to spontaneous ventricular contraction, the first control unit suppresses detection of intracardiac P wave information for a given time interval.

17. (Withdrawn) A distributed cardiac pacing system comprising an electrocardiographic information detection device placed in an atrial myocardium and a plurality of ultra miniature integrated cardiac pacemakers placed in a ventricular myocardium;

wherein the electrocardiographic information detection device comprises:

- a) a first electrocardiographic information detecting means that detects a plurality of electrocardiographic information including at least intracardiac P wave information;
- b) a first transmitting means that modulates detected electrocardiographic information and sends the electrocardiographic information to the ultra miniature integrated cardiac pacemakers; and
- c) a first power unit that supplies a driving current,

wherein the first power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels;

wherein the biological fuel cell comprises an anode electrode and a cathode electrode;

wherein the anode electrode is coated with immobilized oxidative enzymes for biological fuels and mediators;

wherein the biological fuel cell uses blood and/or body fluid as electrolyte solution and utilizes biological fuels and oxygen in blood and/or body fluid;

wherein each of the ultra miniature integrated cardiac pacemakers comprises:

- a) a control unit that outputs at least one control signal;
- b) a heart stimulating means that responds to the control signal and electrically stimulates the ventricular myocardium;
- c) a second electrocardiographic information detecting means that detects a plurality of electrocardiographic information including at least intracardiac QRS complex information;
- d) a second transmitting means that modulates electrocardiographic information and sends the information to other ultra miniature cardiac pacemakers;
- e) a receiving means that receives and demodulates electrocardiographic information sent from other ultra miniature integrated cardiac pacemakers; and
- f) a second power unit that supplies driving power;

wherein the second power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels;

wherein the biological fuel cell comprises an anode electrode and a cathode electrode;

wherein the anode electrode is coated with immobilized oxidative enzymes for biological fuels and mediators;

wherein the biological fuel cell uses blood and/or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in blood and/or body fluid;

wherein electrocardiographic information sent from other ultra miniature integrated cardiac pacemakers is input into the control unit; and the control unit is equipped with a stimulation timing determining means that decides a timing of stimulation to generate the control signal, and a stimulation timing changing means that changes the timing of stimulation to generate the control signal;

wherein if the individual ultra miniature integrated cardiac pacemakers do not detect intracardiac QRS complex information within respective preset times after detection of intracardiac P wave information, the control units of the ultra miniature integrated cardiac pacemakers generate the control signal; whereas if QRS complex information is detected within given times after detection of intracardiac P wave information, the control units generate the control signal synchronous to an earliest timing at which intracardiac QRS complex information is first detected.

18. (Withdrawn) A distributed cardiac pacing system comprising a first ultra miniature integrated cardiac pacemaker placed in a atrial myocardium and a plurality of second ultra miniature integrated cardiac pacemakers placed in a ventricular myocardium.

wherein the first ultra miniature integrated cardiac pacemaker comprises:

- a) a first control unit that outputs at least one first control signal;
- b) a first heart stimulating means that responds to the first control signal and electrically stimulates the atrial myocardium;
- c) a first electrocardiographic information detecting means that detects a plurality of electrocardiographic information including at least intracardiac P wave information;



d) a first transmitting means that modulates the electrocardiographic information and sends the electrocardiographic information to the second ultra miniature cardiac pacemakers;

e) a first receiving means that receives and demodulates the electrocardiographic information sent by the second ultra miniature integrated cardiac pacemakers; and

f) a first power unit that supplies driving power;

wherein the first power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels;

wherein the biological fuel cell comprises an anode electrode and a cathode electrode;

wherein the anode electrode is coated with immobilized oxidative enzymes for biological fuels and mediators;

wherein the biological fuel cell uses blood and/or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in blood and/or body fluid;

wherein electrocardiographic information sent from the second ultra miniature integrated cardiac pacemakers are input into the first control unit; and the first control unit is equipped with a stimulation timing determining means that decides a timing of stimulation to generate the first control signal, and a stimulation timing changing means that changes the timing of stimulation to generate the first control signal;

wherein each of the second ultra miniature integrated cardiac pacemakers comprises:

a) a second control unit that outputs a second control signal;

- b) a second heart stimulating means that responds to the second control signal and electrically stimulates the ventricular myocardium;
- c) a second electrocardiographic information detecting means that detects a plurality of electrocardiographic information including at least intracardiac QRS complex information;
- d) a second transmitting means that modulates the electrocardiographic information and sends the electrocardiographic information to the first and other second ultra miniature integrated cardiac pacemakers;
- e) a second receiving means that receives and demodulates the electrocardiographic information sent from the first and the other second ultra miniature integrated cardiac pacemakers; and
- f) a second power unit that supplies driving power;

wherein the second power unit is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels;

wherein the biological fuel cell comprises an anode electrode and a cathode electrode;

wherein the anode electrode is coated with immobilized oxidative enzymes for biological fuels and mediators;

wherein the biological fuel cell uses blood and/or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in blood and/or body fluid;

wherein the electrocardiographic information sent from the first and other second ultra miniature integrated cardiac pacemakers is input into the second control unit; and the second control unit is equipped with a stimulation timing determining means that decides a timing of stimulation to generate

the second control signal, and a stimulation timing changing means that changes the timing of stimulation to generate the second control signal;

wherein the first control unit generates the first control signal if intracardiac P wave information is not detected within a given time, and suppresses generation of the first control signal if intracardiac P wave information is detected within a given time;

wherein the second control unit of the second ultra miniature integrated cardiac pacemakers generate the second control signal if intracardiac QRS complex information is not detected by individual ultra miniature integrated cardiac pacemakers within the respectively preset times after detection of intracardiac P wave information; whereas if intracardiac QRS complex information is detected within given times after detection of intracardiac P wave information, the second control units generate control signals synchronous to the earliest timing at which intracardiac QRS complex information is detected;

wherein if one of the second ultra miniature integrated cardiac pacemakers detects intracardiac QRS complexes due to spontaneous ventricular contraction, the first control unit suppresses detection of intracardiac P wave information for a given time interval.